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Ms. Kathy Wilson
Compliance Specialist
Parmalat Canada Bakery Division
P.O. Box 9052
135 Otonabee Drive
Kitchener, Ontario N2G 4J3

Re: 21 CFR 130.17(f) - Temporary Marketing Permit for "White Chocolate" under Docket
No. 93P-03 10

Dear Ms. Wilson:

This is to acknowledge your letters from June 1, 1999, July 14, 1999, August 16, 1999, and your faxes from July 6, 1999, and July 20, 1999, to the Food and Drug Administration (FDA) accepting the agency's invitation to participate in the extended temporary market testing of "white chocolate" that was granted to Hershey Foods Corporation (59 FR 67302, December 29, 1994). The agency is granting a temporary market permit that will allow for the market testing of a product that contains white chocolate chunks and macadamia nuts in a buttery cookie base.

For the purpose of this permit, the name of the test product will be "Parmalat Bed and Breakfast White Chocolate Chunk and Macadamia Cookies." The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9.

The white chocolate component of the product differs from the standardized chocolate products in that: (1) it is prepared without the nonfat components of the ground cacao nibs, but contains the fat (cocoa butter) expressed from the ground cacao nibs; and (2) safe and suitable antioxidants are added. In all other respects, the white chocolate component would conform to the cacao product standards.

Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes, of 22,680 kilograms (50,000 pounds) of white chocolate in 73,000 cases of 6 x 8 ounces (226 grams) of white chocolate chunk & macadamia cookie packages, beginning when the test product is introduced into interstate commerce.

The test product will be manufactured at Mrs. Alison's, 1 Cookie Cutter Lane, Highway 92 East, Plant City, Florida 33566. The product will be distributed in St. Louis, Missouri, Kansas City, Missouri, New York, New Jersey, Connecticut, Pennsylvania, and Ohio.

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We believe that the term "made with real butter" is misleading because the product contains vegetable shortening and natural butter flavor. While the final labels should not be printed before the temporary market permit is granted, we notice that the final labels were submitted to the agency on August 16, 1999. We also recognize that this issue had not been previously discussed with you. Therefore, the final labels submitted with your August 16, 1999, letter may be used for market test purposes of your product until your current label inventory is exhausted. However, at the next printing, the statement "made with real butter" must be removed or modified to read "made with vegetable oil, real butter, and butter flavor." Otherwise, the label that you submitted for the test food is acceptable for the purpose of this market test.

While this permit is in effect, FDA will refrain from recommending regulatory action against shipments of "white chocolate" covered by this permit on the grounds that the food fails to comply with the standards of identity for certain chocolate products, e.g., chocolate liquor (21 CFR 163.111), sweet chocolate (21 CFR 163.123), milk chocolate (21 CFR 163.130) buttermilk chocolate (21 CFR 163.135), skim milk chocolate (21 CFR 163.140) or mixed dairy product chocolates (21 CFR 163.145).

Sincerely yours,

Gerard L. McCowin
Acting Director
Office of Food Labeling
Center for Food Safety
and Applied Nutrition

cc:	GCF- 1	HFS-150 (CCO)
	HFA-224	HFS- 15 1 (McCowin)
	HFA-305	HFS-155 (Foret)
	HFS-1	HFS-158 (Satchell, Hockensmith, s/f, f/f)
	HFS-4	HFS-636 (Wade)
	HFS-22 (project 65745)	

Prepared by: HFS-158:CFerre-Hockensmith:7/7/99:parmalat.tmp
Revised:HFS-158:CFERRE-HOCKENSMITH:8/5/99 per FSATCHELL comments
JFORET:8/6/99 per JFORET comments:9/3/99 per FSATCHELL comments
Init by: FSATCHELL:8/9/99
FSATCHELL:9/9/99
WKELKER:9/13/99
F/t:sls:9/14/99